



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/510,644

10/08/2004

Akihiko Mizutani

MIZUTANI3

4955

1444 7590 09/04/2008
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,644	Applicant(s) MIZUTANI ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment and remarks, which were filed on 7 May 2008.
- Applicants' arguments, filed on 7 May 2008 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made.

* * * * *

Election/Restrictions

Applicants argue that claim 13 should be rejoined since, "...it is directed to the elected subject matter, and moreover is a linking claim." (See remarks, page 3).

Examiner respectfully submits that claim 13 includes a limitation which is dependent upon a withdrawn claim from a non-elected group, i.e., claim 11, which is directed to a method for manufacturing a soft capsule formulation. Furthermore, examiner respectfully disagrees with the notion that claim 13 is a linking claim, since no claim depends from claim 13. As such, examiner respectfully submits that claim 13 is properly withdrawn.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,893,658 ("Iida") in view of U.S. Patent No. 3,784,684 ("Bossert").

Iida discloses a light stable soft capsule formulation (see col. 3, lines 7-18) comprising:

- the shell containing a non-water soluble light-shielding agent of instant claim 1 and 19(see col. 2, lines 1-7);
- the non-water-soluble light-shielding agent of instant claim 1 and 19 (see col. 3, lines 21-23);
- the 200 μ m thickness of instant claim 1 (see claim 1);
- the medicament encapsulated by the shell of instant claim 1 (see col. 2, line 49);
- the titanium oxide of instant claim 3 (see col. 3, lines 7-18);
- the seamless shell of instant claim 5 (see col. 5, lines 18-40);
- the light-unstable medicament of instant claim 6 (see col. 2, line 49);
- the medicament suspended in a liquid base of instant claim 7 (see col. 5, line 10);
- the vitamin D derivative of instant claim 8 (see col. 2, line 49);
- the gelatin of instant claim 9 (see col. 4, line 16)'
- the unit dose of instant claim 14 (see col. 1, lines 5-6);
- the capsule of instant claim 15 (see col. 1, lines 5-6); and

- the non-water-soluble light-shielding agent of instant claim 18 (see col. 3, lines 21-23).

lida differs from the instant application in that it does not disclose the concentration of non-water-soluble light-shielding agent recited in claims 1, 18, and 19. However, a concentration of non-water-soluble light-shielding agent overlapping with the range being claimed, i.e. 5%, is disclosed in Bossert (see col. 3, lines 67-68).

lida explain that the disclosed formulation is beneficial because it provides “excellent stability to light and heat and good discrimination.” See col. 2, lines 39-40.

While lida does not explicitly teach the percentages of instant claims 16 and 17, or the capsule size of instant claim 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and size through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration and size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage range or size. The prior art discloses a titanium dioxide of up to 5%, as explained above (see Bossert; col. 3, lines 67-68).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a light stabilized soft capsule formulation comprising a shell containing titanium oxide, and a vitamin D derivative encapsulated in the shell, as taught by Iida et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in excellent stability to light and heat and good discrimination, as explained by Iida, et al.



Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618